

Amendments to the Claims

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

Claim 1 (currently amended): A method for preparing an article of manufacture comprising a stent and a coating disposed thereon, the coating comprising a first layer and a second layer, the first layer comprising a polymer film with a biologically active agent dispersed therein, and the second layer comprising an antithrombogenic heparinized polymer comprising a macromolecule, a hydrophobic material, and heparin bound together with covalent bonds, wherein the macromolecule comprises a protein or a biopolymer, the method comprising:

cleaning the stent with a washing agent,

preparing the first layer by combining the polymer and biologically active agent with a solvent, thereby forming a polymer and biologically active agent mixture and applying the mixture to the stent,

preparing the second layer by combining the ~~hydrophobic~~ antithrombogenic heparinized polymer with a solvent and applying the second layer by immersing the stent in the ~~hydrophobic~~

antithrombogenic heparinized polymer and solvent solution and then drying the stent.

Claim 2 (original): The method of claim 1 further comprising adding a second biologically active agent to the polymer and biologically active agent mixture.

Claim 3 (original): The method of claim 1 wherein applying the first layer coating comprises dipping the stent into the polymer and biologically active agent mixture.

Claim 4 (original): The method of claim 1 wherein applying the first layer coating comprises spraying the polymer and biologically active agent mixture onto the stent.

Claim 5 (currently amended): A method for preventing burst release of a biologically active agent dispersed in a thin film polymer layer on a stent comprising applying a second layer over the thin film polymer layer; said second layer being comprised of a hydrophobic heparinized polymer comprising a macromolecule, a hydrophobic material, and heparin bound together by covalent bonds, wherein the macromolecule comprises a protein or a biopolymer.

Claim 6 (currently amended): A method for inhibiting thrombosis in a medical device having a surface in contact with an organic fluid comprising coating the surface of the medical device with an antithrombogenic heparinized polymer layer comprising a macromolecule, a hydrophobic material, and heparin bound together by covalent bonds, wherein the macromolecule comprises a protein or a biopolymer.

Claim 7 (original): The method of claim 6 further comprising applying a lowermost coating, said lowermost coating disposed under the hydrophobic heparinized polymer layer and comprising an polymer having a biologically active agent dispersed therein.

Claim 8 (previously presented): The method of claim 1 wherein the polymer film is selected from polyurethanes, polyethylene terephthalate, PLLA-poly-glycolic acid (PGA) copolymer (PLGA), polycaprolactone, poly-(hydroxybutyrate/hydroxyvalerate) copolymer, poly(vinylpyrrolidone), polytetrafluoroethylene, poly(2-hydroxyethylmethacrylate), poly(etherurethane urea), silicones, acrylics, epoxides, polyesters, urethanes, parlenes, polyphosphazene polymers, fluoropolymers, polyamides, polyolefins, and mixtures thereof.

Claim 9 (previously presented): The method of claim 1 wherein the biologically active agent dispersed in the first layer is selected from antithrombotics, anticoagulants, antiplatelet agents, thrombolytics, antiproliferatives, anticancer drugs, antiinflammatory drugs, agents that inhibit restenosis, smooth muscle cell inhibitors, antibiotics, and mixtures thereof.

Claim 10 (previously presented): The method of claim 1 wherein the first layer comprises a second biologically active agent dispersed therein.

Claims 11-12 (canceled)

Claim 13 (currently amended): The method of claim ~~11~~ 1 wherein the ~~proteins are~~ protein is selected from protamine, polylysine, polyaspartic acid, polyglutamic acid, and their derivatives and copolymers.

Claim 14 (currently amended): The method of claim ~~11~~ 1 wherein the ~~biopolymers are~~ biopolymer is selected from polysaccharides, gelatin, collagen, alginate, hyaluronic acid, alginic acid, carrageenan, chondroitin, pectin, chitosan, and their derivatives and copolymers.

Claim 15 (currently amended): The method of claim 1 wherein the hydrophobic material is selected from octadecylamine, alkanolic amine, bile acids, sterols, alkanolic acids, and mixtures thereof.

Claim 16 (previously presented): The method of claim 1 wherein the heparin is selected from recombinant heparin, heparin derivatives, and heparin analogues.

Claim 17 (new): A method for preparing an article of manufacture comprising a stent and a coating disposed thereon, the coating comprising a first layer and a second layer, the first layer comprising a polymer film with a biologically active agent dispersed therein, and the second layer comprising an antithrombogenic heparinized polymer comprising a macromolecule, a hydrophobic material, and heparin bound together with covalent bonds, wherein the macromolecule comprises a protein selected from protamine, polylysine, polyaspartic acid, polyglutamic acid, and their derivatives and copolymers, the method comprising:

cleaning the stent with a washing agent,

preparing the first layer by combining the polymer and biologically active agent with a solvent, thereby forming a polymer and biologically active agent mixture and applying the mixture to the stent,

preparing the second layer by combining the antithrombogenic heparinized polymer with a solvent and applying the second layer by immersing the stent in the antithrombogenic heparinized polymer and solvent solution and then drying the stent.

Claim 18 (new): A method for preparing an article of manufacture comprising a stent and a coating disposed thereon, the coating comprising a first layer and a second layer, the first layer comprising a polymer film with a biologically active agent dispersed therein, and the second layer comprising an antithrombogenic heparinized polymer comprising a macromolecule, a hydrophobic material, and heparin bound together with covalent bonds, wherein the macromolecule comprises a biopolymer selected from polysaccharides, gelatin, collagen, alginate, hyaluronic acid, alginic acid, carrageenan, chondroitin, pectin, chitosan, and their derivatives and copolymers, the method comprising:

cleaning the stent with a washing agent,

preparing the first layer by combining the polymer and biologically active agent with a solvent, thereby forming a polymer and biologically active agent mixture and applying the mixture to the stent,

preparing the second layer by combining the antithrombogenic heparinized polymer with a solvent and applying the second layer

by immersing the stent in the antithrombogenic heparinized polymer and solvent solution and then drying the stent.

Claim 19 (new): A method for preparing an article of manufacture comprising a stent and a coating disposed thereon, the coating comprising a first layer and a second layer, the first layer comprising a polymer film with a biologically active agent dispersed therein, and the second layer comprising an antithrombogenic heparinized polymer comprising a macromolecule, a hydrophobic material, and heparin bound together with covalent bonds, wherein the hydrophobic material is selected from octadecylamine, alkanolic amine, bile acids, sterols, alkanolic acids, and mixtures thereof, the method comprising:

cleaning the stent with a washing agent,

preparing the first layer by combining the polymer and biologically active agent with a solvent, thereby forming a polymer and biologically active agent mixture and applying the mixture to the stent,

preparing the second layer by combining the antithrombogenic heparinized polymer with a solvent and applying the second layer by immersing the stent in the antithrombogenic heparinized polymer and solvent solution and then drying the stent.